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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/373,984 08/16/99 SU

X 70862/93137

EXAMINER

HM22/0329

MCKENNA & CUNEO, L.L.P.
1900 K STREET, NW
WASHINGTON DC 20006

TUNG, J	
ART UNIT	PAPER NUMBER

1656

DATE MAILED:

03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/373,984

Applicant(s)

Su et al.

Examiner

Joyce Tung

Group Art Unit

1656



☒ Responsive to communication(s) filed on 1/4/01

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) 14-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 and 20-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-25 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ *notice to comply.*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1656

Response to Amendment

1. The amendment filed 1/04/2001 has been entered.
2. Claims 1-17, 24-43 and 50-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8, and 10-22 of copending Application No. 09/358,664.
3. Regarding the non-statutory double patenting rejection, since a terminal disclaimer has not been filed, the rejection is maintained.
4. The rejection of claims 1-13 and 20-24 under 35 U.S.C. 112, second paragraph in section 6a of the Office action mailed 10/5/2000 is withdrawn because of the argument.
5. The rejection of claims 1-13 and 20-24 under 35 U.S.C. 112, second paragraph in section 6b of the Office action mailed 10/5/2000 is maintained. The response argues that the term "proportional" refers to the exponential amplification of nucleic acid. The argument has not been found persuasive because the exponential amplification of nucleic acid is not proportional amplification. It is still unclear how the term is defined in the specification. Thus, the rejection is maintained.
6. Regarding the rejection of claims 1-12 under 35 U.S.C. 102(b) anticipated by Kwoh et al., the response argues that Kwoh et al. do not teach the proportional amplification with a four-enzyme mix for the amplification steps. The limitation that the four enzyme mix is used in the reaction is not in claims 1-12. Therefore, the rejection is maintained.

Art Unit: 1656

7. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwoh et al.

(Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177).

8. Regarding the rejection of claims 1, 13, and 20-24 under 35 U.S.C. 103(a) over Kwoh et al. in view of Goller et al., Compton and Schnipelsky et al. respectively, the response argues that none of the references above teach or suggest the proportional amplification of a nucleic acid population and there is no motivation to combine the references of Goller et al., Compton and Schnipelsky et al. to make instant invention with reasonable expectations of success. The argument has not been found persuasive because the limitation, for example, "a single reaction vessel" and "without organic extraction and precipitation" as discussed in pg 3, second paragraph of the response is not in claim language. Thus, the rejection is maintained.

9. Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al. (Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177) in view of Goller et al. (Oncogene, 1998, Vol. 16, pg. 2945-2948).

10. Claims 1 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al. (Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177) in view of Compton (Nature, 1991, Vol. 350(7), pg. 91-92).

11. Claims 1 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al. (Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177) in view of Schnipelsky et al. (5,229,297).

Art Unit: 1656

12. Regarding complying the Sequence Rules, the CRF diskette filed on 1/4/2001 is not fully responsive to the communication mailed 10/05/2000 for the reason(s) set forth on the attached Notice of Comply With the Sequence Rules or CRF Diskette Problem Report.

Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response withing the response period set forth in this Office action.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 103

13 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al. (Proc. Natl. Acad. Sci. USA, 1989, Vol. 86, pg. 1173-1177) as applied to claim 1 in section 8 of the Office action mailed 10/5/2000, and further in view of Sooknanan et al. (WO 96/17079).

Kwoh et al. disclose a method of amplifying RNA involving a double stranded cDNA synthesis and then the cDNA is used as template to produce multiple copies of RNA (See pg. 1171, the Abstract). The target nucleic acid can be total RNA (See pg. 1173, column 2, fifth paragraph) or DNA (See pg. 1173, the Abstract). The total RNA inherits that there is mRNA included. The procedure of Kwoh et al. is one reaction procedure based upon the description of

Art Unit: 1656

the procedure and involves reverse transcriptase and RNA polymerases (See pg. 1174, column 1).

The procedure of Kwoh et al. does not using four enzymes in the reaction as claimed in claim 25.

Sooknanan et al. disclose terminal repeat amplification method in which the method provides a single medium comprising RNA polymerase, DNA polymerase and RNase (See the Abstract) and ligase (See pg. 8, first paragraph).

The teachings of Kwoh et al. and Sooknanan et al. suggest the limitations of claim 25 in which claim 25 recites further limitations of claim 1 that four enzymes are use in the reaction.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Kwoh et al. and Sooknanan et al. to make instant invention with reasonable expectation of success because the method of Kwoh et al. provides efficiency of steps to quantitatively produce RNA for specific detection (See pg. 1173, column 2, second paragraph) and the method of Sooknanan et al is enhanced NASA² in which the number of steps is reduced and eliminates the addition of a promoter sequence to derived DNA (See pg. 5, lines 21-24). Thus, it would have been prima facie obvious to carry out the method as claimed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1656

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal

Application/Control Number: 09/373,984

Page 7

Art Unit: 1656

Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 14, 2001

A handwritten signature in black ink, appearing to read "Eggerton Campbell". The signature is written in a cursive, flowing style.

**EGGERTON A. CAMPBELL
PRIMARY EXAMINER**